



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2014-0679; FRL-9963-02]**

**Cyclaniliprole; Pesticide Tolerances and Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of cyclaniliprole in or on multiple commodities that are identified and discussed later in this document. ISK Biosciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). Additionally, this regulation also establishes an exemption from the requirement of a tolerance for indirect or inadvertent residues of cyclaniliprole on multiple commodities identified and discussed later in this document.

**DATES:** This regulation is effective *[insert date of publication in the Federal Register]*.

Objections and requests for hearings must be received on or before *[insert date 60 days after date of publication in the Federal Register]*, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0679, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the

Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Michael L. Goodis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0679 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0679, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of April 6, 2015 (80 FR 18327) (FRL-9924-00), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8253) by ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, OH 44077. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide cyclaniliprole, 3-bromo-*N*-[2-bromo-4-chloro-6-[[[1-cyclopropylethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, in or on the following commodities: Pome Fruit (Crop Group 11-10) at 0.3 parts per million (ppm); Tree Nuts (Crop Group 14-12) at 0.02 ppm; Stone Fruit (Crop Group 12-12) at 0.7 ppm; Fruiting Vegetables (Crop Group 8-10) at 0.2 ppm; Cucurbit Vegetables, (Crop Group 9) at 0.2 ppm; and Small Fruit Vine Climbing Subgroup, except Fuzzy Kiwifruit (Crop Group 13-07F) at 0.9 ppm. Additionally tolerances are requested for residues of cyclaniliprole in or on the crops in the proposed Crop Subgroup 4-14A, Leafy greens subgroup at 7.0 ppm, including amaranth, Chinese; amaranth, leafy; aster, Indian; blackjack; cat's whiskers; chervil, fresh leaves; cham-chwi; cham-namul; chipilin; chrysanthemum, garland; cilantro, fresh leaves; corn salad; cosmos; dandelion; dang-gwi; dillweed; dock; dol-nam-mul; ebolo; endive; escarole; fameflower; feather cockscomb; good king henry; huauzontle; jute, leaves; lettuce, bitter; lettuce, head; lettuce, leaf; orach; parsley, fresh leaves; plantain, buckhorn; primrose, English; purslane, garden; purslane, winter; radicchio; spinach; spinach, malabar; spinach, New Zealand; spinach, tanier; swiss chard; and violet, Chinese; crops in the proposed Crop Subgroup 4-14B, *Brassica* leafy greens subgroup at 15 ppm, including arugula; broccoli raab; broccoli, Chinese; cabbage, abyssinian; cabbage, seakale; Chinese cabbage, bok choy; collards; cress, garden; cress, upland; hanover salad; kale; maca; mizuna; mustard greens; radish, leaves; rape greens; rocket, wild; shepherd's purse; turnip greens; and watercress; crops in the proposed Crop Subgroup 22B, Leaf petiole vegetable subgroup at 7.0 ppm, including Cardoon; celery; celery, Chinese; fuki; rhubarb; udo; zuiki; and

the crops in the proposed Crop Group 5-14, *Brassica* Head and Stem Vegetable at 1.5 ppm, including broccoli; Brussels sprouts; cabbage; cabbage, Chinese, napa; and cauliflower.

Tolerances are also requested for residues of cyclaniliprole in or on the following animal feed commodities: almond, hulls at 8.0 ppm; apple, wet pomace at 0.96 ppm; and in the following animal tissues and meat byproducts: Cattle, fat at 0.08 ppm; cattle, kidney at 0.08 ppm; cattle, liver at 0.1 ppm; cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; goat, fat at 0.08 ppm; goat, kidney at 0.08 ppm; goat, liver at 0.1 ppm; goat, meat at 0.02 ppm; goat, meat byproducts at 0.02 ppm; horse, fat at 0.08 ppm; horse, kidney at 0.08 ppm; horse, liver at 0.1 ppm; horse, meat at 0.02 ppm; horse, meat byproducts at 0.02 ppm; milk at 0.01 ppm; sheep, fat at 0.08 ppm; sheep, kidney at 0.08 ppm; sheep, liver at 0.1 ppm; sheep, meat at 0.02 ppm; and sheep, meat byproducts at 0.02 ppm. In addition, a tolerance was requested for imported Tea (dried and instant) at 40 ppm. That document referenced a summary of the petition prepared by ISK Biosciences Corporation, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

In the **Federal Register** of November 23, 2015 (80 FR 72941) (FRL-9936-73), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing ISK's amendment to its pesticide petition (PP 4F8253). The amended petition requested, in addition to the tolerances requested in the original petition, an exemption from the requirement of a tolerance for indirect or inadvertent residues of cyclaniliprole in or on all food commodities, not already covered by a tolerance. That document referenced a summary of the petition prepared by ISK Biosciences Corporation, the petitioner, which is available in the docket, <http://www.regulations.gov>. A comment was received on the notice of filing. EPA's response to that comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary from what was requested by the petitioner for multiple commodities. The reasons for these changes are explained in Unit IV.D.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyclaniliprole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyclaniliprole follows.

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

No single or repeated dose study performed by any route of exposure produced an adverse effect following cyclaniliprole exposure below, at, or above the limit dose (1,000 mg/kg/day). In short- and long-term studies in rats and mice, the most consistent finding was adaptive liver effects, which often consisted of slight increases in liver weight without associated clinical chemistry and histopathological changes, and it was seen mostly at or above the limit dose (1,000 mg/kg/day). In dogs, both subchronic and chronic studies showed increases in liver weight, centrilobular hepatocellular hypertrophy, and elevated levels of alkaline phosphatase (ALP) at sub-limit dose levels. However, these findings were not considered as adverse because of the following: (1) ALP increase in dogs is a common laboratory finding and could be attributed to many factors such as corticosterone release, young dogs often have high and variable ALP values related to bone growth, cholestasis, and pharmacologically mediated hepatic drug metabolizing enzyme induction; (2) no histopathological changes were seen at any dose level tested; (3) the liver effects showed no progression of toxicity or increase in the number of parameters affected in the chronic study (1-year) relative to the subchronic study; and (4) no liver effects were seen in toxicity studies in rats and mice at or above the limit dose (1,000 mg/kg/day). In addition, a structurally related chemical, chlorantraniliprole, tested up to the limit dose in dogs did not demonstrate liver effects.

No toxicity was seen in rat and rabbit developmental toxicity and in rat reproduction studies which were tested up to the limit dose (1,000 mg/kg/day). Therefore, there is no evidence that cyclaniliprole produces increased susceptibility with prenatal or postnatal exposures. Cyclaniliprole is classified as "Not likely to be Carcinogenic to Humans" based on no increase in treatment-related tumor incidence in the chronic toxicity study in rats and in carcinogenicity studies in rats and mice. Cyclaniliprole produced no genotoxicity. A dermal

toxicity study tested at the limit dose did not produce any systemic toxicity, which was consistent with the finding of low dermal absorption.

Specific information on the studies received for cyclaniliprole as well as the no-observed-adverse-effect-level (NOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Cyclaniliprole: Human Health Risk Assessment for the Proposed New Insecticide Active Ingredient” dated September 12, 2015 in docket ID number EPA-HQ-OPP-2014-0679.

Based on the analysis of the available cyclaniliprole toxicological studies, there is no adverse toxicity seen in any of the required submitted toxicology studies, and no toxicity endpoint and point of departure are established for human health risk assessment.

Cyclaniliprole is proposed for use on a variety of crops. Humans could potentially be exposed to cyclaniliprole residues in food because cyclaniliprole may be applied directly to growing crops. These applications can also result in cyclaniliprole reaching surface and ground water, both of which can serve as sources of drinking water. There are no proposed uses in residential settings; therefore, there are no anticipated residential exposures.

Based on the toxicological profile of cyclaniliprole, EPA has concluded that the FFDCA requirements to retain an additional safety factor for protection of infants and children and to consider cumulative effects do not apply. Section 408(b)(2)(C) requires an additional tenfold margin of safety in the case of threshold risks, which are not present in this case. Section 408(b)(2)(D)(v) requires consideration of information concerning cumulative effects of substances that have a common mechanism of toxicity, which cyclaniliprole does not have.

Based on the available data indicating a lack of adverse effects from exposure to cyclaniliprole, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cyclaniliprole.



#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Method JSM0269 was developed for plant commodities, and Method JSM0277 was developed for livestock commodities. Residues of cyclaniliprole are extracted from crops using acetonitrile and cleaned up by solid phase extraction. Extracted residue levels are determined by liquid chromatography with tandem mass spectrometry (LC-MS/MS). Residues of cyclaniliprole are extracted from livestock using acetonitrile and cleaned up by liquid-liquid partition with hexane followed by SPE. Extracted residue levels are determined by LC-MS/MS in positive ion spray mode.

Multiresidue methods testing data have been submitted for cyclaniliprole and NK-1375. The data indicate that the multiresidue methods (Protocols A through G) are not suitable for the analysis of cyclaniliprole, so the multiresidue methods cannot serve as enforcement methods. The multiresidue data have been sent to FDA.

Adequate enforcement methodology (LC-MS/MS) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an

international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for cyclaniliprole.

#### *C. Response to Comments*

A comment was received from an anonymous commenter objecting to EPA requesting denial of this petition and stating that “food should not be contaminated with these chemicals.” The existing legal framework provided by section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) states that tolerances may be set when the pesticide meets the safety standard imposed by that statute. As required by that statute, EPA conducted a comprehensive assessment of cyclaniliprole, including its potential for carcinogenicity. Based on its assessment of the available data, the Agency believes that given the observed lack of toxicity of this chemical, no risks of concern are expected. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to cyclaniliprole.

#### *D. Revisions to Petitioned-For Tolerances*

Tolerances were requested for individual crops in the proposed Crop Subgroup 4-14A, Leafy greens subgroup at 7.0 ppm; crops in the proposed Crop Subgroup 4-14B, *Brassica* leafy greens subgroup at 15 ppm; crops in the proposed Crop Subgroup 22B, Leaf petiole vegetable subgroup at 7.0 ppm and the crops in the proposed Crop Group 5-14: *Brassica* Head and Stem Vegetable at 1.5 ppm. These crop groups were proposed in a Proposed Rule that published in the **Federal Register** of November 14, 2014 (79 FR 68153). In the time since the petition was initially filed, these crop group/subgroups have been established, although with a slightly

different numbering based on the year in which the crop groups were finalized, i.e., since the rule was published in 2016, the groups end in a -16, instead of -14 when they were proposed. See May 3, 2016 (85 FR 26471). Therefore, EPA is establishing the subgroup/group tolerances as requested but with the updated names with one exception. EPA is not establishing a tolerance for subgroup 22B since residue field trial data (celery) were not provided to support the establishing a tolerance for the commodities in subgroup 22B.

Additionally, the EPA is establishing a tolerance for Vegetable, leafy, group 4-16 at 15 ppm instead of the requested tolerance for residues in or on the leafy greens subgroup 4-16A at 7.0 ppm and *Brassica* leafy greens subgroup 4-16B at 15 ppm. Based on the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures and residue data for head lettuce, leaf lettuce, and spinach, the tolerance level would be 8.0 ppm for leafy greens subgroup 4-16A. However, instead of establishing the two subgroup tolerances, in order to harmonize with Canada which has established a crop group, Leafy Vegetables (CG 4-13) maximum residue level (MRL) at 15 ppm, EPA is establishing a tolerance for Vegetable, leafy, group 4-16 at 15 ppm.

The EPA is also establishing lower tolerance levels than requested for the following commodities because the residue of concern is parent only instead of parent and its metabolite NK-1375: almond hulls, reduced from 8 to 6.0 ppm; wet apple pomace, reduced from 0.96 to 0.50 ppm; Vegetable, *Brassica*, head and stem, group 5-16 reduced from 1.5 to 1.0 ppm; cucurbit vegetables, crop group 9, reduced from 0.2 to 0.15 ppm; small vine climbing fruit, except fuzzy kiwifruit, crop group 13-07F, reduced from 0.9 to 0.80 ppm; and for the following commodities for each animal (cattle, goat, horse, and sheep)—fat, reduced from 0.08 to 0.015 ppm; kidney (now included in meat byproducts), reduced from 0.08 to 0.015 ppm; meat,

reduced from 0.02 to 0.01 ppm; meat byproducts, reduced from 0.02 to 0.015 ppm; and liver, reduced from 0.1 to 0.015 ppm.

Based on OECD tolerance calculation procedures, EPA is also establishing higher tolerance levels than requested for the following commodities: the stone fruit crop group 12-12, increased from 0.7 to 1.0 ppm; the tree nuts crop group 14-12, increased from 0.02 to 0.03 ppm, and tea, dried leaves, increased from 40 to 50 ppm. No tolerance is needed for tea, instant (dry form) since residues are covered by the tolerance on tea, dried.

EPA is establishing an increased tolerance on milk from 0.01 ppm to 0.015 ppm to harmonize with Canada.

Finally, tolerances were requested for residues in/on kidney and liver of cattle, goat, horse, and sheep. According to current EPA policy, residues for liver and kidney will be covered by tolerances for residues in/on meat byproducts so separate tolerances are not needed.

## **V. Conclusion**

Although the lack of toxicity supports a safety finding for an exemption from the requirement of tolerance for all crops, EPA is establishing tolerances for residues resulting from direct applications to certain commodities because the petitioner requested them for international trade purposes. Tolerances are established for residues of cyclaniliprole, 3-bromo-*N*-[2-bromo-4-chloro-6-[[[(1-cyclopropylethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, in or on Pome Fruit (Crop Group 11–10) at 0.30 parts per million (ppm); Nut, tree (Crop Group 14–12) at 0.03 ppm; Stone Fruit (Crop Group 12–12) at 1.0 ppm; Fruiting Vegetables (Crop Group 8–10) at 0.20 ppm; Cucurbit Vegetables, (Crop Group 9) at 0.15 ppm; Small Fruit Vine Climbing Subgroup except Fuzzy Kiwifruit (Crop Group 13–07F) at 0.80 ppm; Vegetable, leafy, group 4-16 at 15 ppm; Vegetable, *Brassica*, head and stem, group 5-16 at 1.0 ppm; Milk at 0.015 ppm; tea, dried leaves at 50 ppm; Almond, hulls at 6.0 ppm; Apple, wet

pomace at 0.50 ppm; cattle, goat, horse, and sheep fat at 0.015 ppm; cattle, goat, horse, and sheep meat at 0.01 ppm; and cattle, goat, horse, and sheep meat byproducts at 0.015 ppm.

Additionally, an exemption from the requirement of a tolerance is established for indirect or inadvertent residues of cyclaniliprole, 3-bromo-*N*-[2-bromo-4-chloro-6-[[1-(cyclopropylethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, in or on all raw agricultural commodities, except for those commodities with tolerances established.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 30, 2017.

Richard P. Keigwin, Jr.,  
*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.694 to subpart C to read as follows:

**§ 180.694 Cyclaniliprole; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the insecticide cyclaniliprole, including its metabolites and degradates, in or on the commodities in the table below.

Compliance with the tolerance levels specified below is to be determined by measuring only cyclaniliprole, 3-bromo-N-[2-bromo-4-chloro-6-[[[(1-cyclopropylethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, in or on the commodity.

Commodity	Parts per million
Almond, hulls	6.0
Apple, wet pomace	0.50
Cattle, fat	0.015
Cattle, meat	0.01
Cattle, meat byproducts	0.015
Fruit, pome, group 11-10	0.30
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	0.80
Fruit, stone, group 12-12	1.0
Goat, fat	0.015
Goat, meat	0.01
Goat, meat byproducts	0.015
Horse, fat	0.015
Horse, meat	0.01
Horse, meat byproducts	0.015
Milk	0.015
Nut, tree, group 14-12	0.03
Sheep, fat	0.015
Sheep, meat	0.01
Sheep, meat byproducts	0.015
Tea, dried <sup>1</sup>	50



Vegetable, <i>Brassica</i> , head and stem, group 5-16	1.0
Vegetable, cucurbit, group 9	0.15
Vegetable, fruiting, group 8-10	0.20
Vegetable, leafy, group 4-16	15

<sup>1</sup>There are no U.S. registrations for Tea.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

3. Add § 180.1344 to subpart D to read as follows:

**§ 180.1344 Cyclaniliprole; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for indirect and inadvertent residues of the insecticide cyclaniliprole, including its metabolites and degradates, in or on all raw agricultural commodities not listed in paragraph (a) of § 180.694, when residues are present therein as a result of subsequent uptake by crops rotated into fields where the crops in § 180.694 (a) were treated with cyclaniliprole.